(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 498.103 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A—GENERAL PROVISIONS

SUBCHAPTER B—OIG AUTHORITIES

SUBCHAPTER A—GENERAL PROVISIONS

PART 1000—INTRODUCTION; GENERAL DEFINITIONS

Subpart A—[Reserved]

Subpart B—Definitions

Sec.

AUTHORITY: 42 U.S.C. 1320 and 1395hh.

SOURCE: 51 FR 34766, Sept. 30, 1986, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Definitions

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Health Care Financing Administration.

Beneficiary means any individual eligible to have benefits paid to him or her, or on his or her behalf, under Medicare or any State health care program.

CFR stands for Code of Federal Regulations.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FR stands for FEDERAL REGISTER.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual, or ordered or prescribed by a physician, (either as an employee or in his or her own capacity), a provider, or other supplier of services.

HCFA stands for Health Care Financing Administration.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

Inspector General means the Inspector General for Health and Human Services.

Medicaid means medical assistance provided under a State plan approved under Title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under Title XVIII of the Act.

OIG means the Office of Inspector General within HHS.

PRO stands for Utilization and Quality Control Peer Review Organization.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[51 FR 34766, Sept. 30, 1986 as amended at 57 FR 3329, Jan. 29, 1992]

§ 1000.20 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Carrier means an entity that has a contract with HCFA to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Entitled means that an individual meets all the requirements for Medicare benefits.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of Title XVIII of the Act.

Intermediary means an entity that has a contract with HCFA to determine and make Medicare payments for Part

A or Part B benefits payable on a cost basis and to perform other related functions.

Medicare Part A means the hospital insurance program authorized under Part A of Title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of Title XVIII of the Act.

Provider means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or effective November 1, 1983 through September 30, 1986, a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of Title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[51 FR 34766, Sept. 30, 1986, as amended at 57 FR 3329, Jan. 29, 1992]

§ 1000.30 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Provider means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in sections 1905(a)(1) through (18) of the Act.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

Subpart A—General Provisions

Subpart B—Mandatory Exclusions

Subpart C—Permissive Exclusions

Subpart D—Waivers and Effect of Exclusion

Subpart E—Notice and Appeals

Subpart F—Reinstatement into the Programs

AUTHORITY: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395y(e), and 1395hh.

SOURCE: 57 FR 3330, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicare and certain State health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993]

§ 1001.2 Definitions.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Exclusion means that items and services furnished by a specified individual or entity will not be reimbursed under Medicare or the State health care programs.

HHS means Department of Health and Human Services.

OIG means Office of Inspector General of the Department of Health and Human Services.

PRO means Utilization and Quality Control Peer Review Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982 (42 U.S.C. 1320c–3).

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. Where the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA) or the Public Health Service (PHS) has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition shall not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(a) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Public Health Service as a health manpower shortage area for that medical specialty, as listed in 42 CFR part 5, appendices B–F;

(b) Is a sole community hospital, as defined in §412.92 of this title; or

(c) Is the only source for specialized services in a defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State health care program means:

(a) A State plan approved under title XIX of the Act (Medicaid),

(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program), or

(c) Any program receiving funds under title XX of the Act or from any allotment to a State under such title (Block Grants to States for Social Services).

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and §1002.305 of this chapter.

Subpart B—Mandatory Exclusions

§1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program, or

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients. The conviction need not relate to a patient who is a program beneficiary.

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to Medicare and the State health care programs of $1,500 or more. (The entire amount of financial loss to such programs will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made to the programs);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) The sentence imposed by the court included incarceration;

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record; or

(6) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare or State health care programs as a result of improper billings.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to Medicare and the State health care programs due to the acts that resulted in the conviction, and similar acts, is less than $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare or any of the State health care programs, or

(ii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

Subpart C—Permissive Exclusions

§ 1001.201 Conviction relating to program or health care fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a program operated by, or financed in whole or in part by, any Federal, State or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, resulted in financial loss of $1,500 or more to a government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of

financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made.);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to a government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than $1,500;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.301 Conviction relating to obstruction of an investigation.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation into any criminal offense described in §§ 1001.101 or 1001.201.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference with, or obstruction of, the investigation caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare or State health care programs;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992]

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law.

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals or the Medicare or State health care programs;

(iii) The sentence imposed by the court included incarceration; or

(iv) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for shortening the period of exclusion—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) Except as provided in paragraph (c) of this section, an exclusion imposed in accordance with this section will never be for a period of time less than the period during which an individual's or entity's license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

(ii) The individual or entity has a prior criminal, civil or administrative sanction record; or

(iii) The acts (or similar acts) had or could have had a significant adverse impact on the financial integrity of the programs.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that

set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with a State licensing authority resulted in the sanctioning of other individuals or entities; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with § 1001.3001 if the individual or entity obtains a valid license in the State where the license was originally revoked, suspended, surrendered or otherwise lost.

(c) *Exceptions*—(1) *Length of exclusion.* If, prior to the notice of exclusion by the OIG, the licensing authority of a State (other than the one in which the individual's or entity's license had been revoked, suspended, surrendered or otherwise lost), being fully apprised of all of the circumstances surrounding the prior action by the licensing board of the first State, grants the individual or entity a license or takes no significant adverse action as to a currently held license, an exclusion imposed in accordance with this section may be for a period of time less than that prescribed by paragraph (b)(1) of this section.

(2) *Consideration of early reinstatement.* If an individual or entity that has been excluded in accordance with this section fully and accurately discloses the circumstances surrounding this action to a licensing authority of a different State, and that State grants the individual or entity a new license or takes no significant adverse action as to a currently held license, the OIG will consider a request for early reinstatement.

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term ''or otherwise sanctioned'' in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under the Federal or State health care program had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is greater than 3 years; or

(iii) The individual or entity has a prior criminal, civil or administrative record.

(3) Only the following factors may be considered mitigating and a basis for shortening the period of exclusion—

(i) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is less than 3 years;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the sanctioning of other individuals or entities; or

(iii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

(4) The OIG will normally not consider a request for reinstatement in accordance with § 1001.3001 until the period of exclusion imposed by the OIG has expired.

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;

(iii) The individual or entity has a prior criminal, civil or administrative sanction record; or

(iv) The violation resulted in financial loss to Medicare or the State health care programs of $1,500 or more.

(3) Only the following factors may be considered mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) Circumstances for exclusion. The OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization (HMO), as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) HMO or competitive medical plan providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under a plan, waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) The OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) HCFA's HMO compliance office; or

(6) Any other sources deemed appropriate by the OIG.

(c) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (c)(2) and (c)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service had or could have had a serious adverse effect; or

(iv) The entity has a criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the entity are not available.

(iii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

§ 1001.901 False or improper claims.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) The individual's or entity's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(4) Other matters as justice may require.

§ 1001.951 Fraud and kickbacks and other prohibited activities.

(a) *Circumstance for exclusion.* (1) Except as provided for in paragraph (a)(2)(ii) of this section, the OIG may exclude any individual or entity that it determines has committed an act described in section 1128B(b) of the Act.

(2) With respect to acts described in section 1128B of the Act, the OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove

that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is the subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion.* (1) The following factors will be considered in determining the length of exclusion in accordance with this section—

(i) The nature and circumstances of the acts and other similar acts;

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on program beneficiaries or other individuals or the Medicare or State health programs;

(iii) The excluded individual's or entity's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(iv) Any other facts bearing on the nature and seriousness of the individual's or entity's misconduct.

(2) It will be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the—

(A) Sanctioning of other individuals or entities, or

(B) Imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services provided by the individual or entity are not available.

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment Interests.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following two categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of items and services, all of the following five applicable standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 781 (b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms equally available to the public through trading on a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or on the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous

12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous 12 month period may come from referrals, items or services furnished, or business otherwise generated from investors.

(vii) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

For purposes of paragraph (a) of this section, the following terms apply. *Active investor* means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units of a partnership, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security.

(b) *Space Rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following five standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole

or in part under Medicare or a State health care program.

For purposes of paragraph (b) of this section, the term *fair market value* means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(c) *Equipment rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following five standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (c) of this section, the term *fair market value* means the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(d) *Personal services and management contracts.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following six standards are met—

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

(6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) *Sale of practice.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(1) The period from the date of the first agreement pertaining to the sale

to the completion of the sale is not more than one year.

(2) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

(f) *Referral services.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value between an individual or entity (''participant'') and another entity serving as a referral service (''referral service''), as long as all of the following four standards are met—

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by the participants for the referral service for which payment may be made in whole or in part under Medicare or a State health care program.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) *Warranties.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section—

(1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

(3) The manufacturer or supplier must comply with either of the following two standards—

(i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.

(ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its

obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

For purposes of paragraph (g) of this section, the term *warranty* means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

(h) *Discounts.* As used in section 1128B of the Act, ''remuneration'' does not include a discount, as defined in paragraph (h)(3) of this section, on a good or service received by a buyer, which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program, from a seller as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section:

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within each category—

(i) If the buyer is an entity which reports its costs on a cost report required by the Department or a State agency, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section.

(ii) If the buyer is an entity which is a health maintenance organization or competitive medical plan acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(iii) If the buyer is not an entity described in paragraphs (h)(1)(i) or (h)(1)(ii) of this section, it must comply with all of the following three standards—

(A) The discount must be made at the time of the original sale of the good or service;

(B) Where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and

(C) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section.

(2) With respect to either of the following two categories of buyers, the seller must comply with all of the applicable standards within each category—

(i) If the buyer is an entity described in paragraph (h)(1)(ii) of this section, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is any other individual or entity, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to the Department or a State agency under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice or statement submitted to the buyer, and inform the buyer of its obligations to report such discount; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the

invoice or statement submitted to the buyer, inform the buyer of its obligations under paragraph (h)(1) of this section and, when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied.

(3) For purposes of this paragraph, the term *discount* means a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or a group purchasing organization) for a good or service based on an arms length transaction. The term *discount* may include a rebate check, credit or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished. The term *discount* does not include—

(i) Cash payment;

(ii) Furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service;

(iii) A reduction in price applicable to one payor but not to Medicare or a State health care program;

(iv) A reduction in price offered to a beneficiary (such as a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary);

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration in cash or in kind not explicitly described in this paragraph.

(i) *Employees.* As used in section 1128B of the Act, ''remuneration'' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. For purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) *Group purchasing organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

For purposes of paragraph (j) of this section, the term *group purchasing organization* (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, ''remuneration'' does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to

pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

(l) *Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.* (1) As used in section 1128B of the Act, ''remuneration'' does not include the additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program, as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with HCFA or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by HCFA or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with HCFA or with a State health care program to receive payment for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by HCFA or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased

payments are claimed from Medicare or a State health care program.

(2) For purposes of paragraph (l) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

(m) *Price reductions offered to health plans.* (1) As used in section 1128B of the Act, ''remuneration'' does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with HCFA or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with HCFA or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;

(C) The health plan must fully and accurately report, on the applicable cost report or other claim form filed with the Department or the State health care program, the amount it has paid the contract health care provider

under the agreement for the covered items and services furnished to enrollees; and

(D) The contract health care provider must not claim payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section and the contract health care provider is not paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following six standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State

health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms *contract health care provider, enrollee,* and *health plan* have the same meaning as in paragraph (l)(2) of this section.

[57 FR 3330, Jan. 29, 1992, as amended at 57 FR 52729, Nov. 5, 1992; 61 FR 2135, Jan. 25, 1996]

§1001.953 OIG report on compliance with investment interest safe harbor.

Within 180 days of the effective date of this subpart, the OIG will report to the Secretary on the compliance with §§1001.952(a)(2)(i) and 1001.952(a)(2)(vi).

§1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

(A) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2) or (3) of the Act;

(B) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(B) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(C) Is an officer or director of the entity, if the entity is organized as a corporation;

(D) Is a partner in the entity, if the entity is organized as a partnership;

(E) Is an agent of the entity; or

(F) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof.

(2) For purposes of this section, the term:

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

Ownership interest means an interest in:

(i) The capital, the stock or the profits of the entity, or

(ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) *Length of exclusion.* (1) Except as provided in §1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in §1001.3001(a)(2).

§1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

(3) The entity's prior criminal, civil and administrative sanction record (The lack of any prior record is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct;

(5) The availability of alternative sources of the type of health care services provided by the entity; and

(6) The extent to which the entity knew that the disclosures made were not full or accurate.

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that:

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue;

(4) The individual's or entity's criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(5) The availability of alternative sources of the type of health care items or services provided by the individual or entity.

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or.

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance

with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for the mentally retarded), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for the purposes of reviewing records, documents and other data necessary to the performance of the Inspector General's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of this section, the term—

Failure to grant immediate access means the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Reasonable request means a written request made by a properly identified agent of the Secretary, of a State survey agency or of another authorized entity, during hours that the facility, agency or institution is open for business.

The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definition of *reasonable request* and *immediate access,* and the penalties for failure to comply, including when the exclusion will take effect.

(3) For purposes of paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the term—

Failure to grant immediate access means:

(i) Except where the OIG or State Medicaid fraud control unit reasonably believes that requested documents are about to be altered or destroyed, the failure to produce or make available for inspection and copying requested records upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request;

(ii) Where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to provide access to requested records at the time the request is made.

Reasonable request means a written request for documents, signed by a designated representative of the OIG or the State Medicaid fraud control unit, and made by a properly identified agent of the OIG or a State Medicaid fraud control unit during reasonable business hours, where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX or XX of the Act. The request will include a statement of the authority for the request, the rights of the individual or entity in responding to the request, the definition of *reasonable request* and *immediate access,* and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare or any of the State health care programs, beneficiaries or the public; and

(iv) The entity's prior criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral).

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of

the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 40753, July 30, 1993]

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion.* The OIG may exclude any hospital that HCFA determines has failed substantially to comply with a corrective action plan required by HCFA under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare or any of the State health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare or any of the State health care programs, beneficiaries or the public; and

(5) The hospital's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral).

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* (1) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the Public Health Service (PHS) determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that PHS has taken all reasonable administrative steps to secure repayment of the loans or obligations. If PHS has offered a Medicare offset arrangement as required by section 1892 of the Act, the OIG will find that all reasonable steps have been taken.

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare or State health care programs in determining whether to impose an exclusion.

(4) The OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until such time as PHS notifies the OIG that the default has been cured or the obligations have been resolved to the PHS's satisfaction. Upon such notice, the OIG will inform the individual of his or her right to request reinstatement.

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and''

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in

accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges;

(iv) The physician's prior criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral); and

(v) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992]

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) Circumstance for exclusion. The OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under Part B of the Medicare program (or his or her representative) for:

(i) Services of an assistant at surgery during a cataract operation, or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Peer Review Organization (PRO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the PRO or carrier;

(v) The physician's criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral); and

(vi) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, State health care programs, and all other Executive Branch procurement and nonprocurement programs and activities. The OIG will exclude the individual or entity from the Medicare program and direct State agency administering a State health care program to exclude the individual or entity for the same period. In the case of an individual or entity not eligible to participate in Medicare, the exclusion will still be effective on the date, and for the period, established by the OIG.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare program in accordance with subpart F of this part, no payment will be made by Medicare or any of the State health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, HCFA will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) HCFA will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare or a State health care program warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion, and

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of exclusion.

(4) (i) Notwithstanding the other provisions of this section, payment may be made under Medicare or a State health care program for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(4)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995]

Subpart E—Notice and Appeals

§1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion, and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG proposes to exclude an individual or entity in accordance with §§1001.701 or 1001.801, the individual or entity may submit, in addition to the information described in paragraph (a) of this section, a written request to present evidence or argument orally to an OIG official.

(c) Exception. If the OIG proposes to exclude an individual or entity under the provisions of §§1001.1301, 1001.1401 or 1101.1501, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraphs (a) and (b) of this section will so state.

§1001.2002 Notice of exclusion.

(a) Except as provided in §1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with §1001.1301.

§1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in §1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the date of the notice unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law

judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b)(1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in § 1001.2002.

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant an immediate exclusion, an exclusion will not go into effect unless an ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§ 1001.2001 and 1001.2002.

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with § 1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual or entity is known to be serving as an employee, administrator, operator, or in which the individual or entity is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect HCFA's ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Peer Review Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act; and

(8) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in §1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in §1001.2002 to file a request for such a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a conviction, a determination by another government agency or any other prior determination, the basis for the underlying determination is not reviewable and the individual or entity may not collaterally attack the underlying determination, either on substantive or procedural grounds, in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

Subpart F—Reinstatement into the Programs

§1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraph (a)(2) of this section or in §§1001.501(b)(4) and (c) and 1001.601(b)(4), an excluded individual or entity (other than those excluded in accordance with §§1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion.

(2) An entity under §1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in §1001.3002(c) have been met.

(3) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.

(4) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(b) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual or entity may request reinstatement once the reduced exclusion period expires.

§1001.3002 Basis for reinstatement.

(a) The OIG will authorize reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(3) There is no additional basis under sections 1128 (a) or (b) or 1128A of the Act for continuation of the exclusion.

(b) In making the reinstatement determination, the OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid or satisfactory arrangements have been made to fulfill these obligations;

(4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations; and

(5) For purposes of individuals or entities excluded under part 1004 of this chapter only, the individual's or entity's willingness and ability to provide health care that meets professionally recognized standards.

(c) If the OIG determines that the criteria in paragraphs (a)(2) and (a)(3) of this section have been met, an entity excluded in accordance with §1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—

(1) Has reduced his or her ownership or control interest in the entity below 5 percent;

(2) Is no longer an officer, director, agent or managing employee of the entity; or

(3) Has been reinstated in accordance with paragraph (a) of this section or § 1001.3005.

(d) Reinstatement will not be effective until OIG grants the request and provides notice under § 1001.3003(a)(1). Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in § 1001.3004.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

§ 1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Notify HCFA of the date of the individual's or entity's reinstatement in the Medicare program;

(2) Give written notice to the excluded individual or entity specifying the date when Medicare participation may resume;

(3) Notify State agencies that administer the State health care programs that the individual or entity has been reinstated into the Medicare program; and

(4) To the extent applicable, give notice to those agencies, groups, individuals and others that were originally notified of the exclusion.

(b) If the OIG makes a determination to reinstate an individual or entity under Medicare, the State health care program upon notification from the OIG must automatically reinstate the individual or entity under such program, effective on the date of reinstatement under Medicare, unless—

(1) Reinstatement is not available to such excluded party under State law, or

(2) A longer exclusion period was established in accordance with the State's own authorities and procedures.

§ 1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

(1) Documentary evidence and written argument against the continued exclusion,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be considered until at least one year after the date of denial, or approving the request consistent with the procedures set forth in § 1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§ 1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into the Medicare program retroactive to the effective date of the exclusion when such exclusion is based on—

(1) A conviction that is reversed or vacated on appeal; or

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal.

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, HCFA will make payment for services covered under Medicare that were furnished or performed during the period of exclusion.

(c) The OIG will give notice of a reinstatement under this section in accordance with § 1001.3003(a).

(d) An action taken by OIG under this section will not require any State health care program to reinstate the individual or entity if it has imposed an exclusion under its own authority.

PART 1002—PROGRAM INTEGRITY—STATE–INITIATED EXCLUSIONS FROM MEDICAID

Subpart A—General Provisions

Subpart B—Mandatory Exclusion

Subpart C—Permissive Exclusions

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

AUTHORITY: 42 U.S.C. 1302, 1320a–3, 1320a–5, 1320a–7, 1396(a)(4)(A), 1396(p)(1), 1396a(30), 1396a(39), 1396b(a)(6), 1396b(b)(3), 1396b(i)(2) and 1396b(q).

SOURCE: 57 FR 3343, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§1002.1 Scope and purpose.

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States' obligation to inform the OIG of certain Medicaid-related convictions.

§1002.2 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare program under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

(b) Nothing contained in this part should be construed to limit a State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law.

§1002.3 Disclosure by providers; information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person described in §1001.1001(a)(1) of this chapter.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services program.

(2) The Medicaid agency may refuse to enter into, or terminate, a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

§1002.100 State plan requirement.

The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements.

The agency may impose broader sanctions if it has the authority to do so under State law.

Subpart B—Mandatory Exclusion

§ 1002.203 Mandatory exclusion.

(a) The State agency, in order to receive Federal financial participation (FFP), must provide that it will exclude from participation any HMO, or entity furnishing services under a Waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under § 1001.1001 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under § 1001.1001 of this chapter.

(b) As used in this section, the term—

Exclude includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

Substantial contractual relationship is one in which the sanctioned individual described in § 1001.1001 of this chapter has direct or indirect business transactions with the organization or entity that, in any fiscal year, amount to more than $25,000 or 5 percent of the organization's or entity's total operating expenses, whichever is less. Business transactions include, but are not limited to, contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, space or salaried employment.

Subpart C—Permissive Exclusions

§ 1002.210 Permissive exclusions; general authority.

The State agency must have administrative procedures in place that enable it to exclude an individual or entity for any reason for which the Secretary could exclude such individual or entity under parts 1001 or 1003 of this chapter. The period of such exclusion is at the discretion of the State agency.

§ 1002.211 Effect of exclusion.

(a) *Denial of payment.* Except as provided for in § 1001.1901 (c)(3) and (c)(4)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

(b) *Denial of FFP.* FFP is not available where the State agency is required to deny payment under paragraph (a) of this section. FFP will be reinstated at such time as the excluded individual or entity is reinstated in the Medicaid program.

§ 1002.212 State agency notifications.

When the State agency initiates an exclusion under § 1002.210, it must provide to the individual or entity subject to the exclusion notification consistent with that required in subpart E of part 1001 of this chapter, and must notify other State agencies, the State medical licensing board (where applicable), the public, beneficiaries, and others as provided in §§ 1001.2005 and 1001.2006 of this chapter.

§ 1002.213 Appeals of exclusions.

Before imposing an exclusion under § 1002.210, the State agency must give the individual or entity the opportunity to submit documents and written argument against the exclusion. The individual or entity must also be given any additional appeals rights that would otherwise be available under procedures established by the State.

§ 1002.214 Basis for reinstatement after State agency-initiated exclusion.

(a) The provisions of this section and § 1002.215 apply to the reinstatement in the Medicaid program of all individuals or entities excluded in accordance with § 1002.210, if a State affords reinstatement opportunity to those excluded parties.

(b) An individual or entity who has been excluded from Medicaid may be reinstated only by the Medicaid agency that imposed the exclusion.

(c) An individual or entity may submit to the State agency a request for reinstatement at any time after the

date specified in the notice of exclusion.

§1002.215 Action on request for reinstatement.

(a) The State agency may grant reinstatement only if it is reasonably certain that the types of actions that formed the basis for the original exclusion have not recurred and will not recur. In making this determination, the agency will consider, in addition to any factors set forth in State law—

(1) The conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the agency at the time of the exclusion;

(2) The conduct of the individual or entity after the date of the notice of exclusion; and

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid, or satisfactory arrangements have been made, that fulfill these obligations.

(b) Notice of action on request for reinstatement. (1) If the State agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with §1002.212, specifying the date on which Medicaid program participation may resume.

(2) If the State agency does not approve the request for reinstatement, it will notify the excluded party of its decision. Any appeal of a denial of reinstatement will be in accordance with State procedures and need not be subject to administrative or judicial review, unless required by State law.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

§1002.230 Notification of State or local convictions of crimes against Medicaid.

(a) The State agency must notify the OIG whenever a State or local court has convicted an individual who is receiving reimbursement under Medicaid of a criminal offense related to participation in the delivery of health care items or services under the Medicaid program, except where the State Medicaid Fraud Control Unit (MFCU) has so notified the OIG.

(b) If the State agency was involved in the investigation or prosecution of the case, it must send notice within 15 days after the conviction.

(c) If the State agency was not so involved, it must give notice within 15 days after it learns of the conviction.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

Sec.

AUTHORITY: 42 U.S.C. 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

SOURCE: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

§1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1842(j), 1842(k), 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Pub. L. 99–660 (42 U.S.C. 1320a–7, 1320a–7a, 1320a–7(c), 1320b(10), 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

(i) Have submitted certain prohibited claims under the Medicare, Medicaid, or the Maternal and Child Health Services or Social Services Block Grant programs;

(ii) Seek payment in violation of the terms of an assignment agreement or a limitation on charges or payments under the Medicare program, or a requirement not to charge in excess of the amount permitted under the Medicaid program;

(iii) Give false or misleading information that might affect the decision to discharge a Medicare patient from the hospital;

(iv) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60;

(v) Misuse certain Departmental and Medicare and Medicaid program words, letters, symbols or emblems;

(vi) Violate a requirement of section 1867 of the Act or §489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services, or who engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses, or that do not meet the requirements for physician incentive plans for Medicare specified in §§417.479 (d) through (i) of this title;

(viii) Have submitted certain prohibited claims under the Medicare program;

(ix) Present or cause to be presented a bill or claim for designated health service (as defined in §411.351 of this title) that they know, or should know, were furnished in accordance with a referral prohibited under §411.353 of this title;

(x) Have collected amounts that they know or should know were billed in violation of §411.353 of this title and have not refunded the amounts collected on a timely basis; or

(xi) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of §411.353 of this title.

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.

[57 FR 3345, Jan. 29, 1992, as amended at 59 FR 32124, June 22, 1994; 59 FR 48566, Sept. 22, 1994; 60 FR 16583, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996]

§ 1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

ALJ means an Administrative Law Judge.

Assessment means the amount described in §1003.104, and includes the plural of that term.

Claim means an application for payment for an item or service for which payment may be made under the Medicare, Medicaid, Maternal and Child Health Services Block Grant, or Social Services Block Grant programs.

(a) An item or service for which payment may be made under Medicare, or

(b) An item or service for which medical assistance is provided under a State plan for medical assistance, or

(c) An item or service for which payment may be made under the Maternal and Child Health Services Block Grant program.

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in section

1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Department means the Department of Health and Human Services.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

Exclusion means the temporary or permanent barring of a person from participation in the Medicare program or in a State health care program, and that items or services furnished or ordered by such person are not reimbursed under such programs.

General Counsel means the General Counsel of the Department or his or her designees.

HCFA means the Health Care Financing Administration.

Inspector General means the Inspector General of the Department or his or her designees.

Item or *service* includes (a) any item, device, medical supply or service claimed to have been provided to a patient and listed in an itemized claim for program payment or a request for payment, and (b) in the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's or other health care practitioner's provision of, or failure to provide health care services, and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

Medicare means the program of health insurance for the aged and disabled authorized under Title XVIII of the Act.

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in § 1003.103 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Program means the Medicare, Medicaid, Maternal and Child Health Services Block Grant, and Social Services Block Grant programs.

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with § 1003.102(b)(9) of this part, the 60-

day period from the time the prohibited amounts are collected by the individual or the entity.

[51 FR 34777, Sept. 30, 1986, as amended at 56 FR 28492, June 21, 1991; 57 FR 3345, Jan. 29, 1992; 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 61 FR 13449, Mar. 27, 1996]

§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

(3) An item or service furnished during a period in which the person was excluded from participation in the program to which the claim was made in accordance with a determination made under sections 1128 (42 U.S.C. 1320a–7), 1128A (42 U.S.C. 1320a–7a), 1156 (42 U.S.C. 1320c–5), 1160(b) as in effect on September 2, 1982 (42 U.S.C. 1320c–9(b)), 1842(j)(2) (42 U.S.C. 1395u(j)), 1862(d) as in effect on August 18, 1987 (42 U.S.C. 1395y(d)), or 1866(b) (42 U.S.C. 1395cc(b));

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified; or

(5) A payment that such person knows, or should know, may not be made under § 411.353 of this title.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(1) Has presented or caused to be presented a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act.

(2) Is a non-participating physician under section 1842(j) of the Act and has knowingly and willfully billed—

(i) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(ii) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986.

(3) Is a physician who has knowingly and willfully—

(i) Billed for services as an assistant at surgery during a routine cataract operation, or

(ii) Included in his or her bill the services of an assistant at surgery during a routine cataract operation, and has not received prior approval from the appropriate Peer Review Organization or Medicare carrier for such services based on the existence of a complicating medical condition; or

(4) Has given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence

the decision when to discharge such person or another person from the hospital.

(5) Fails to report information concerning a payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other health care practitioner in accordance with section 421 of Pub. L. 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60.

(6) Improperly discloses, uses or permits access to information reported in accordance with part B of title IV of Pub. L. 99–660, in violation of section 427 of Pub. L. 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of title IV in response to a subpoena or a discovery request is considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660.)

(7) Has made use of the words, letters, symbols or emblems as defined in paragraph (b)(7)(i) of this section in such a manner that such person knew or should have known would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that an advertisement, solicitation or other item was authorized, approved or endorsed by the Department or HCFA, or that such person or organization has some connection with or authorization from the Department or HCFA. Civil money penalties—

(i) May be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department or its programs, for misuse of—

(A) The words ''Department of Health and Human Services,'' ''Health and Human Services,'' ''Health Care Financing Administration,'' ''Medicare,'' or ''Medicaid,'' or any other combination or variation of such words;

(B) The letters ''DHHS,'' ''HHS,'' or ''HCFA,'' or any other combination or variation of such letters; or

(C) A symbol or emblem of the Department or HCFA (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under title II, or envelopes or other stationery used by the Department or HCFA) or any other combination or variation of such symbols or emblems; and

(ii) Will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that makes use of any symbol or emblem, or any words or letters which specifically identifies that agency or instrumentality of the State or political subdivision.

(8) Is a contracting organization that HCFA determines has committed an act or failed to comply with the requirements set forth in §417.500(a) or §434.67(a) of this title or failed to comply with the requirement set forth in §434.80(c) of this title.

(9) Has not refunded on a timely basis, as defined in §1003.101 of this part, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in §411.353 of this title;

(10) Is a physician or entity that enters into—

(i) A cross referral arrangement, for example, whereby the physician owners of entity ''X'' refer to entity ''Y,'' and the physician owners of entity ''Y'' refer to entity ''X'' in violation of §411.353 of this title, or

(ii) Any other arrangement or scheme that the physician or entity knows, or should know, has a principal purpose of circumventing the prohibitions of §411.353 of this title.

(c)(1) The Office of the Inspector General (OIG) may impose a penalty for violations of section 1867 of the Act or §489.24 of this title against—

(i) Any participating hospital with an emergency department that—

(A) Knowingly violates the statute on or after August 1, 1986 or;

(B) Negligently violates the statute on or after May 1, 1991; and

(ii) Any responsible physician who—

(A) Knowingly violates the statute on or after August 1, 1986;

(B) Negligently violates the statute on or after May 1, 1991;

(C) Signs a certification under section 1867(c)(1)(A) of the Act if the physician knew or should have known that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(D) Misrepresents an individual's condition or other information, including a hospital's obligations under this section.

(2) For purposes of this section, a responsible physician or hospital ''knowingly'' violates section 1867 of the Act if the responsible physician or hospital recklessly disregards, or deliberately ignores a material fact.

(d)(1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) In any case in which it is determined that more than one person was responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using, or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) In any case in which it is determined that more than one responsible physician violated the provisions of section 1867 of the Act or of § 489.24 of this title, a penalty may be imposed against each responsible physician.

(5) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

[57 FR 3345, Jan. 29, 1992; 57 FR 9670, Mar. 20, 1992, as amended at 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995]

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b), (c) and (d) of this section, the OIG may impose a penalty of not more than $2,000 for each item or service that is subject to a determination under § 1003.102.

(b) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.102(b)(4), or for each item and service that is subject to a determination under § 1003.102(a)(5) or § 1003.102(b)(9) of this part. The OIG may impose a penalty of not more than $100,000 for each arrangement or scheme that is subject to a determination under § 1003.102(b)(10) of this part.

(c) The OIG may impose a penalty of not more than $11,000[1] for each payment for which there was a failure to report required information in accordance with § 1003.102(b)(5), or for each improper disclosure, use or access to information that is subject to a determination under § 1003.102(b)(6).

(d)(1) The OIG may impose a penalty of not more than $5,000 for each violation resulting from the misuse of Departmental, HCFA, Medicare or Medicaid program words, letters, symbols or emblems as described in § 1003.102(b)(7) relating to printed media, and a penalty of not more than $25,000 in the case of such misuse related to a broadcast or telecast, that is related to a determination under § 1003.102(b)(7).

[1] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134).

(2) For purposes of this paragraph, a violation is defined as—

(i) In the case of a direct mailing solicitation or advertisement, each separate piece of mail which contains one or more words, letters, symbols or emblems related to a determination under § 1003.102(b)(7);

(ii) In the case of a printed solicitation or advertisement, each reproduction, reprinting or distribution of such item related to a determination under § 1003.102(b)(7); and

(iii) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under § 1003.102(b)(7).

(e) For violations of section 1867 of the Act or § 489.24 of this title, the OIG may impose—

(1) Against each participating hospital with an emergency department, a penalty of not more than—

(i) $25,000 for each knowing violation occurring on or after August 1, 1986 and before December 22, 1987;

(ii) $50,000 for each knowing violation occurring on or after December 22, 1987; and

(iii) $50,000 for each negligent violation occurring on or after May 1, 1991, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000; and

(2) Against each responsible physician, a penalty of not more than—

(i) $25,000 for each knowing violation occurring on or after August 1, 1986 and before December 22, 1987;

(ii) $50,000 for each knowing violation occurring on or after December 22, 1987; and

(iii) $50,000 for each negligent violation occurring on or after May 1, 1991.

(f)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization has—

(i) Failed substantially to provide an enrollee with required medically necessary items and services and the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Imposed premiums on enrollees in excess of amounts permitted under section 1876 or title XIX of the Act;

(iii) Acted to expel or to refuse to reenroll a Medicare beneficiary in violation of the provisions of section 1876 of the Act and for reasons other than the beneficiary's health status or requirements for health care services;

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or section 1903(m) of the Act;

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims; or

(vi) Failed to comply with the requirements of §§ 417.479 (d) through (i) of this title for Medicare, and §§ 417.479 (d) through (g) and (i) of this title for Medicaid, regarding certain prohibited incentive payments to physicians.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization with a contract under section 1876 of the Act—

(i) Employs or contracts with individuals or entities excluded, under section 1128 or section 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of services (directly or indirectly) through an excluded individual or entity.

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has—

(i) Misrepresented or falsified information to the Secretary under section 1876 of the Act or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to reenroll a Medicaid recipient because of the individual's health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or section 1903(m) of the Act) with

the contracting organization by Medicare beneficiaries and Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.

(4) If enrolles are charged more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.

(5) The OIG will impose an additional $15,000 penalty for each individual not enrolled when HCFA determines that a contracting organization has committed a violation described in paragraph (f)(3)(ii) of this section.

(6) For purposes of paragraph (f) of this section, a violation is each incident where a person has committed an act listed in §417.500(a) or §434.67(a) of this title, or failed to comply with a requirement set forth in §434.80(c) of this title.

[57 FR 3346, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 48566, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 61 FR 52301, Oct. 7, 1996]

§1003.104 Amount of assessment.

A person subject to a penalty determined under §1003.102(a) may be subject, in addition, to an assessment of not more than twice the amount claimed for each item or service which was a basis for the penalty. The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.

§1003.105 Exclusion from participation in Medicare and State health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, the following persons may be subject, in lieu of or in addition to any penalty or assessment, to an exclusion from participation in Medicare for a period of time determined under §1003.107. The OIG will also direct each appropriate State agency to exclude the person from each health care program for the same period of time—

(i) Any person who is subject to a penalty or assessment under §1003.102 (a) or (b)(1) through (b)(4).

(ii) Any responsible physician who—

(A) Knowingly violates section 1867 of the Act or §489.24 of this title on or after December 22, 1987, but before July 1, 1990;

(B) Knowingly and willfully, or negligently, violates section 1867 of the Act or §489.24 of this title on or after July 1, 1990 but before May 1, 1991; or

(C) Commits a gross and flagrant, or repeated, violation of section 1867 of the Act or §489.24 of this title on or after May 1, 1991. For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety or well-being of the individual who seeks emergency examination and treatment or places that individual unnecessarily in a high-risk situation.

(2) Nothing in this section will be construed to limit the Department's authority to impose an exclusion without imposing a penalty.

(b)(1) With respect to determinations under §1003.102 (b)(2) or (b)(3), or with respect to violations occurring on or after December 22, 1987 and before July 1, 1990 under §1003.105(a)(1)(ii), a physician may not be excluded if the OIG determines that he or she is the sole community physician or the sole source of essential specialized services in a community.

(2)(i) With respect to any exclusion based on liability for a penalty or assessment under §1003.102 (a), (b)(1), or (b)(4), the OIG will consider an application from a State agency for a waiver if the person is the sole community physician or the sole source of essential specialized services in a community. With respect to any exclusion imposed under §1003.105(a)(1)(ii), the OIG will consider an application from a State agency for a waiver if the physician's exclusion from the State health care program would deny beneficiaries access to medical care or would otherwise cause hardship to beneficiaries.

(ii) If a waiver is granted, it is applicable only to the State health care program for which the State requested the waiver.

(iii) If the OIG subsequently obtains information that the basis for a waiver

no longer exists, or the State agency submits evidence that the basis for the waiver no longer exists, the waiver will cease and the person will be excluded from the State health care program for the remainder of the period that the person is excluded from Medicare.

(iv) The OIG notifies the State agency whether its request for a waiver has been granted or denied.

(v) The decision to deny a waiver is not subject to administrative or judicial review.

(3) For purposes of this section, the definitions contained in §1001.2 of this chapter for ''sole community physician'' and ''sole source of essential specialized services in a community'' apply.

(c) When the Inspector General proposes to exclude a nursing facility from the Medicare and Medicaid programs, he or she will, at the same time he or she notifies the respondent, notify the appropriate State licensing authority, the State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to exclude the facility.

[59 FR 32125, June 22, 1994]

§1003.106 Determinations regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with §1003.102 (a), (b)(1), (b)(4), (b)(9), and (b)(10), the Department will take into account—

(i) The nature of the claim, request for payment or information given, and the circumstances under which it was presented or given;

(ii) The degree of culpability of the person submitting the claim or request for payment, or giving the information;

(iii) The history of prior offenses of the person submitting the claim or request for payment, or giving the information;

(iv) The financial condition of the person presenting the claim or request for payment, or giving the information;

(v) The completeness and timeliness of the refund with respect to §1003.102(b)(9);

(vi) The amount of financial interest involved with respect to §1003.102(b)(10); and

(vii) Such other matters as justice may require.

(2) In determining the amount of any penalty in accordance with §§1003.102 (b)(5) and (b)(6), the Department will take into account—

(i) The nature and circumstances resulting in the failure to report medical malpractice payments or the improper disclosure of information;

(ii) The degree of culpability of the person in failing to provide timely and complete malpractice payment data or in improperly disclosing, using or permitting access to information;

(iii) The materiality, or significance of omission, of the information to be reported with regard to medical malpractice judgments or settlements, or the materiality of the improper disclosure of, or use of, or access to information;

(iv) Any prior history of the person with respect to violations of these provisions; and

(v) Such other matters as justice may require.

(3)(i) In determining the amount of any penalty in accordance with §1003.102(b)(7), the OIG will take into account—

(A) The nature and objective of the advertisement, solicitation or other communication, and the degree to which it has the capacity to deceive members of the public;

(B) The degree of culpability of the individual, organization or entity in the use of the prohibited words, letters, symbols or emblems;

(C) The frequency and scope of the violation, and whether a specific segment of the population was targeted;

(D) The prior history of the individual, organization or entity in its willingness or refusal to comply with informal requests to correct violations;

(E) The history of prior offenses of the individual, organization or entity in its misuse of Departmental and program words, letters, symbols and emblems;

(F) The financial condition of the individual, organization or entity involved with the violation; and

(G) Such other matters as justice may require.

(ii) The use of a disclaimer of affiliation with the United States Government, the Department or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.102(b)(7).

(4) In determining the amount of any penalty in accordance with § 1003.102(c), the OIG takes into account—

(i) The degree of culpability of the respondent;

(ii) The seriousness of the condition of the individual seeking emergency medical treatment;

(iii) The prior history of offenses of the respondent in failing to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer;

(iv) The respondent's financial condition;

(v) The nature and circumstances of the violation; and

(vi) Such other matters as justice may require.

(5) In determining the appropriate amount of any penalty in accordance with § 1003.103(f), the OIG will consider as appropriate—

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under section 1876(i)(6) or section 1903(p)(2) of the Act, from contracting with or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to reenroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee or other entity under section 1876 or section 1903(m) of the Act;

(vii) The extent to which the failure to provide medically necessary services could be attributed to a prohibited inducement to reduce or limit services under a physician incentive plan and the harm to the enrollee which resulted or could have resulted from such failure. It would be considered an aggravating factor if the contracting organization knowingly or routinely engaged in any prohibited practice which acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization;

(viii) The history of prior offenses by the contracting organization or principals of the contracting organization, including whether, at any time prior to determination of the current violation or violations, the contracting organization or any of its principals were convicted of a criminal charge or were held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(ix) Such other matters as justice may require.

(b) *Determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered—

(1) *Nature and circumstances of the incident.* It should be considered a mitigating circumstance if all the items or services or incidents subject to a determination under § 1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or incidents, and the total amount claimed or requested for such items or services was less than $1,000. It should be considered an aggravating circumstance if—

(i) Such items or services or incidents were of several types, occurred over a lengthy period of time;

(ii) There were many such items or services or incidents (or the nature and circumstances indicate a pattern of claims or requests for payment for

such items or services or a pattern of incidents);

(iii) The amount claimed or requested for such items or services was substantial; or

(iv) The false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission.

(2) *Degree of culpability.* It should be considered a mitigating circumstance if the claim or request for payment for the item or service was the result of an unintentional and unrecognized error in the process respondent followed in presenting claims or requesting payment, and corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in § 1003.102(a)(3) or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or limitation on payment under § 1003.102(b); or

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital.

(3) *Prior offenses.* It should be considered an aggravating circumstance if at any time prior to the incident or presentation of any claim or request for payment which included an item or service subject to a determination under § 1003.102, the respondent was held liable for criminal, civil or administrative sanctions in connection with a program covered by this part or any other public or private program of reimbursement for medical services.

(4) *Other wrongful conduct.* It should be considered an aggravating circumstance if there is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance.

(5) *Financial condition.* It should be considered a mitigating circumstance if imposition of the penalty or assessment without reduction will jeopardize the ability of the respondent to continue as a health care provider. In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

(6) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to assure the achievement of the purposes of this part.

(c) In determining the amount of the penalty and assessment to be imposed for every item or service or incident subject to a determination under §§ 1003.102(a) and (b)(1) through (b)(4)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximium permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close or at the maximum permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (d) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§ 1003.102(a) and (b)(1) through (b)(4).

(d) In considering the factors listed in paragraph (a)(4) of this section, for violations subject to a determination

under § 1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) Nature and circumstances of the incident. It would be considered a mitigating circumstance if, where more than one violation exists, the appropriate items or services not provided were:

(i) Few in number, or

(ii) Of the same type and occurred within a short period of time.

It would be considered an aggravating circumstance if such items or services were of several types and occurred over a lengthy period of time, or if there were many such items or services (or the nature and circumstances indicate a pattern of such items or services not being provided).

(2) Degree of culpability. It would be considered a mitigating circumstance if the violation was the result of an unintentional, unrecognized error, and corrective action was taken promptly after discovery of the error.

(3) Failure to provide required care. It would be considered an aggravating circumstance if the failure to provide required care was attributable to an individual or entity that the contracting organization is expressly prohibited by law from contracting with or employing.

(4) Use of excluded individuals. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in the prohibited practice of contracting or employing, either directly or indirectly, individuals or entities excluded from the Medicare program under section 1128 or section 1128A of the Act.

(5) Routine practices. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in any discriminatory or other prohibited practice which has the effect of denying or discouraging enrollment by individuals whose medical condition or history indicates a need for substantial future medical services.

(6) Prior offenses. It would be considered an aggravating circumstance if at any time prior to determination of the current violation or violations, the contracting organization or any of its principals was convicted on criminal charges or held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services. The lack of prior liability for criminal, civil, or administrative sanctions by the contracting organization, or the principals of the contracting organization, would not necessarily be considered a mitigating circumstance in determining civil money penalty amounts.

(e)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution and administrative review of the case.

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by § 1003.126, or to compromise any penalty and assessment as provided by § 1003.128.

[57 FR 3347, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 36086, July 15, 1994; 59 FR 48567, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996]

§ 1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in § 1003.106(a).

(b) With respect to determinations to exclude a person under §§ 1003.102(a) or (b)(1) through (b)(4), the Department considers those circumstances described in § 1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) In determining whether to exclude a physician under §§ 1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987

and before July 1, 1990, under §1003.105(a)(1)(ii), the Department also considers the access of beneficiaries to physicians' services.

(d) Except as set forth in paragraph (e), the guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by §1003.126.

(e) An exclusion based on a determination under §§1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987 and before July 1, 1990, under §1003.105(a)(1)(ii), may not exceed 5 years.

[59 FR 32126, June 22, 1994]

§1003.108 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

[59 FR 32126, June 22, 1994]

§1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in Medicare or any State health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent, written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

(1) Reference to the statutory basis for the penalty, assessment and exclusion;

(2) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment and exclusion are proposed (except in cases where the Inspector General is relying upon statistical sampling in accordance with §1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);

(3) The reason why such claims, requests for payment or incidents subject the respondent to a penalty, assessment and exclusion; the amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(5) Any circumstances described in §1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of respondent's right to a hearing, and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion in accordance with §1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.

(c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

[57 FR 3348, Jan. 29, 1992, as amended at 59 FR 32126, June 22, 1994]

§1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §1003.109(a), the Inspector General may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the

respondent by certified mail, return receipt requested, of any penalty, assessment, and exclusion that has been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, assessment, and exclusion, with respect to which he or she has not requested a hearing.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3348, Jan. 29, 1992]

§ 1003.114 Collateral estoppel.

(a) Where a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part that—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

[57 FR 3348, Jan. 29, 1992]

§ 1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time prior to a final decision by the Secretary. Thereafter, the General Counsel has such exclusive authority.

§ 1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

[57 FR 3348, Jan. 29, 1992]

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of HCFA, except in the case of the Maternal and Child Health Services Block Grant program, where the collection will be the responsibility of the PHS, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.

(b) A penalty and assessment imposed under this part may be compromised by the General Counsel, after consultation with the Inspector General, and may be recovered in a civil action brought in the United States district court for the district where the claim was presented, or where the respondent resides.

(c) The amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992]

§ 1003.129 Notice to other agencies.

Whenever a penalty, assessment or exclusion become final, the following organizations and entities will be notified about such action and the reasons for it—the appropriate State or local medical or professional association; the appropriate Peer Review Organization; as appropriate, the State agency responsible or the administration of each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization

(including the Medicare and Medicaid State survey agencies); and the long-term care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

[57 FR 3349, Jan. 29, 1992]

§ 1003.132 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.109(a) of this part, within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[57 FR 3349, Jan. 29, 1992]

§ 1003.133 Statistical sampling.

(a) In meeting the burden of proof set forth in § 1005.15, the Inspector General may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in § 1003.102 that were presented or caused to be presented by respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in § 1003.102.

(b) Once the Inspector General has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Inspector General will then be given the opportunity to rebut this evidence.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992]

§ 1003.134 Effect of exclusion.

The effect of an exclusion will be as set forth in § 1001.1901 of this chapter.

[57 FR 3349, Jan. 29, 1992]

§ 1003.135 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of §§ 1001.3001 through 1001.3004 of this chapter.

[57 FR 3349, Jan. 29, 1992]

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A PEER REVIEW ORGANIZATION

Subpart A—General Provisions

Sec.

Subpart B—Sanctions Under the PRO Program; General Provisions

Subpart C—PRO Responsibilities

Subpart D—OIG Responsibilities

Subpart E—Effect and Duration of Exclusion

Subpart F—Appeals

AUTHORITY: 42 U.S.C. 1302 and 1320c–5.

SOURCE: 60 FR 63640, Dec. 12, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 1004.1 Scope and definitions.

(a) *Scope.* This part implements section 1156 of the Act by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from peer review organizations (PROs) when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise—

Dentist is limited to licensed doctors of dental surgery or dental medicine.

Economically means the services are provided at the least expensive, medically appropriate type of setting or level of care available.

Exclusion means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.

Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

Health care service or services means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.

Health professional shortage area (HPSA) means an area designated by the Secretary and defined in 42 CFR 5.2.

Metropolitan Statistical Area means an area as defined by the Executive Office of Management and Budget.

Obligation means any of the obligations specified at section 1156(a) of the Act.

Other person means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.

Pattern or care means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.

Pharmacy professional is a term limited to individuals who are licensed or registered to provide pharmaceutical services.

Podiatric professional is a term limited to licensed doctors of podiatric medicine.

Practice area means the location where over 50 percent of the practitioner's or other person's patients are seen.

Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.

Primary medical care professional is a term limited to:

(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or

(ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.

Pro area means the geographic area subject to review by a particular PRO.

Provider means a hospital or other health care facility, agency, or organization.

Psychiatric professional is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.

Rural means any area outside an urban area.

Rural health professional shortage area means any health professional shortage area located outside a Metropolitan Statistical Area.

Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a PRO.

Serious risk includes situations that may involve the risk of unnecessary

treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

State health care program means a State plan approved under title XIX, any program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the PRO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

(a) Provided economically and only when, and to the extent, medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of medical necessity and quality in the form and fashion and at such time that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under the law, a practitioner or other person may be—

(a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act for a period of no less than 1 year; or

(b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering of health care services (or services furnished at the medical direction or on the prescription of a physician) that were medically improper or unnecessary, required to pay an amount of up to $10,000 for each instance in which improper or unnecessary services were furnished or ordered (or prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

[62 FR 23143, Apr. 29, 1997]

Subpart C—PRO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) When the PRO identifies situations where an obligation specified in § 1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§ 1004.40 and 1004.60.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the PRO finds that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of admissions; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The PRO report to the OIG must comply with the provisions of § 1004.80.

(e) If a practitioner or other person relocates to another PRO area prior to a finding of a violation or sanction recommendation, and the originating PRO—

(1) Is able to make a finding, the originating PRO must, as appropriate, close the case or forward a sanction recommendation to the OIG; or

(2) Cannot make a finding, the originating PRO must forward all documentation regarding the case to the PRO with jurisdiction, and notify the practitioner or other person of this action.

(f) The PRO must deny payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the PRO identifies the services or items. It must report the findings to the Health Care Financing Administration.

§ 1004.40 Action on identification of a violation.

When a PRO identifies a violation, it must—

(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and

(b) Send the practitioner or other person written notice of the identification of a violation containing the following information—

(1) The obligation(s) involved;

(2) The situation, circumstances or activity that resulted in a violation;

(3) The authority and responsibility of the PRO to report violations of any obligation under section 1156(a) of the Act;

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;

(5) The sanction that the PRO could recommend to the OIG;

(6) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice additional information or a written request for a meeting with the PRO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—

(i) It will be held within 30 days of receipt by the PRO of the request, but may be extended for good cause;

(ii) The practitioner or other person may have an attorney present; and

(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person's behalf; and

(7) A copy of the material used by the PRO in arriving at its finding except for PRO deliberations, as set forth in § 476.139 of this part.

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the PRO—

(a) The PRO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;

(b) No physician member of the PRO panel may be in direct economic competition with the practitioner or other person being considered for sanction;

(c) The PRO must ensure that no physician member of the PRO panel has a substantial bias for or against the practitioner or other person being considered for sanction;

(d) At least one member of the PRO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);

(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the PRO that a practitioner or other

person be sanctioned may not vote on that recommendation at the meeting;

(g) The PRO may allow the practitioner or other person 5 working days after the meeting to provide the PRO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 PRO finding of a violation.

(a) On the basis of any additional information received, the PRO will affirm or modify its finding. If the PRO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the PRO. If the finding has been resolved to the PRO's satisfaction, the PRO may modify its initial finding or recommendation or close the case.

(b) The PRO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in § 1004.70.

(c) At least one member of the PRO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the PRO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 PRO action on final finding of a violation.

If the finding is not resolved to the PRO's satisfaction as specified in § 1004.60(a), the PRO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in § 1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered; and

(c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§ 1004.80 PRO report to the OIG.

(a) *Manner of reporting.* If the violation(s) identified by the PRO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.

(b) *Content of report.* The PRO report must include the following information—

(1) Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence, including reports of conversations with the practitioner or other person regarding the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;

(6) The PRO's finding that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in

a substantial number of cases or is gross and flagrant;

(7) A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the PRO's initial finding;

(8) A copy of the CAP that was developed and documentation of the results of such plan;

(9) The number of admissions by the practitioner or other person reviewed by the PRO during the period in which the violation(s) were identified;

(10) The professional qualifications of the PRO's reviewers; and

(11) The PRO's sanction recommendation.

(c) *PRO recommendation.* The PRO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable;

(4) The availability of alternative sources of services in the community, with supporting information; and

(5) The county or counties in which the practitioner or other person furnishes services.

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 1004.90 Basis for recommended sanction.

The PRO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioner's or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the PRO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the PRO of the date it received the PRO's report and recommendation.

(b) *Review.* The OIG will review the PRO report and recommendation to determine whether—

(1) The PRO has followed the regulatory requirements of this part; and

(2) A violation has occurred.

(c) *Rejection of the PRO recommendation.* If the OIG decides that a sanction is not warranted, it will notify the PRO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the PRO of the sanction recommendation that the recommendation is rejected.

(d) *Decision to sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the PRO;

(2) The type of offense;

(3) The severity of the offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and

(7) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.110(f).

(f) *Monetary penalty.* If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.110 (a)–(e).

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 1004.110 Notice of sanction.

(a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice must specify—

(1) The legal and factual basis for the determination;

(2) The sanction to be imposed;

(3) The effective date and, if appropriate, the duration of the exclusion;

(4) The appeal rights of the practitioner or other person;

(5) The opportunity and the process necessary to provide alternative notification as set forth in paragraphs (d) and (e) of this section; and

(6) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) *Patient notification.* (1)(i) The OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. In order to elect this option, the sanctioned practitioner or other person must, within 30 calendar days from receipt of the OIG notice, inform both new and existing patients through written notice—based on a suggested (non-mandatory) model provided to the sanctioned individual by the OIG—of the sanction and, in the case of an exclusion, its effective date. Receipt of the OIG notice is presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary. Within this same period, the practitioner or other person must also sign and return the certification that the OIG will provide with the notice. For purposes of this section, the term ''all existing patients'' includes all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last 3 years. In addition, the practitioner or other person must notify all prospective patients orally at the time such persons request an appointment. If the sanctioned party is a hospital, it must notify all physicians who have privileges at the hospital, and must post a notice in its emergency room, business office and in all affiliated entities regarding the exclusion. In addition, for purposes of this section, the term ''in all affiliated entities'' encompasses all entities and properties in which the hospital has a direct or indirect ownership interest of 5 percent or more and any management, partnership or control of the entity.

(ii) The certification will provide that the practitioner or other person—

(A) Has informed each of his, her or its patients in writing that the practitioner or other person has been sanctioned, or if a hospital, has informed all physicians having privileges at the hospital that it has been sanctioned;

(B) If excluded from Medicare and the State health care programs, has informed his, her or its existing patients in writing that the programs will not pay for items and services furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by the practitioner or other person until they are reinstated, or if a hospital, has provided this information to all physicians having privileges at that hospital;

(C) If excluded from Medicare and State health care programs, will provide prospective patients—or if a hospital, physicians requesting privileges at that hospital prior to furnishing or ordering (or in the case of an excluded physician, medically directing or prescribing) services—oral information of both the sanction and that the programs will not pay for services provided and written notification of the same at the time of the provision of services;

(D) If excluded from Medicare and State health care programs and is an entity such as a hospital, has posted a notice in its emergency room, business office and in all affiliated entities that the programs will not pay for services provided; and

(E) Certifies to the truthfulness and accuracy of the notification and the statements in the certification.

(2) If the sanctioned practitioner or other person does not inform his, her or its patients *and* does not return the required certification within the 30-day period, or if the sanctioned practitioner or other person returns the certification within the 30-day period but the OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, the OIG—

(i) Will see that the public is notified directly of the identity of the sanctioned practitioner or other person, the finding that the obligation has been

violated, and the effective date of any exclusion; and

(ii) May consider this failure to adhere to the certification obligation as an adverse factor at the time the sanctioned practitioner or other person requests reinstatement.

(3) If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with §1004.140(a) and requests such a preliminary hearing, and if the administrative law judge (ALJ) decides that he, she or it poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receipt of the ALJ's decision to provide certification to the OIG in accordance with §1004.110(d)(1). The date of receipt is presumed to be 5 days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

(e) Notice of the sanction is also provided to the following entities as appropriate—

(1) The PRO that originated the sanction report;

(2) PROs in adjacent areas;

(3) State Medicaid fraud control units and State licensing and accreditation bodies;

(4) Appropriate program contractors and State agencies;

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations and Federally-funded community health centers where the practitioner or other person works;

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the PRO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the PRO recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of sanction is also provided as specified in paragraph (e) of this section.

[60 FR 63640, Dec. 12, 1995; 61 FR 1841, Jan. 24, 1996, as amended at 62 FR 23143, Apr. 29, 1997]

Subpart E—Effect and Duration of Exclusion

§1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in §1001.1901 of this chapter.

§1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in §1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§1004.140 Appeal rights.

(a) *Right to preliminary hearing.* (1)(i) A practitioner or other person excluded from participation in Medicare and any State health care programs under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner's or other person's practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(i) of this section unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner's or other person's continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ's decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal to the DAB. Exclusions in such instances will be effective 5 days after receipt of the ALJ decision in the OIG headquarters.

(6)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. the hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for

the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in §1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(c) *Rights to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.

AUTHORITY: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

SOURCE: 57 FR 3350, Jan. 29, 1992, unless otherwise noted.

§1005.1 Definitions.

Civil money penalty cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose civil money penalties under Medicare or the State health care programs.

DAB refers to the Departmental Appeals Board or its delegatee.

Exclusion cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose exclusions under Medicare or the State health care programs.

§1005.2 Hearing before an administrative law judge.

(a) A party sanctioned under any criteria specified in parts 1001, 1003 and 1004 of this chapter may request a hearing before an ALJ.

(b) In exclusion cases, the parties to the proceeding will consist of the petitioner and the IG. In civil money penalty cases, the parties to the proceeding will consist of the respondent and the IG.

(c) The request for a hearing will be made in writing, signed by the petitioner or respondent or by his or her attorney. The request must be filed within 60 days after the notice, provided in accordance with §§1001.2002, 1001.2003 or 1003.109, is received by the petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

(d) The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.

(e) The ALJ will dismiss a hearing request where—

(1) The petitioner's or the respondent's hearing request is not filed in a timely manner;

(2) The petitioner or respondent withdraws his or her request for a hearing;

(3) The petitioner or respondent abandons his or her request for a hearing; or

(4) The petitioner's or respondent's hearing request fails to raise any issue which may properly be addressed in a hearing.

§ 1005.3 Rights of parties.

(a) Except as otherwise limited by this part, all parties may—

(1) Be accompanied, represented and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this part;

(4) Agree to stipulations of fact or law which will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of section 206 of title II of the Act, which authorizes the Secretary to specify or limit these fees.

§ 1005.4 Authority of the ALJ.

(a) The ALJ will conduct a fair and impartial hearing, avoid delay, maintain order and assure that a record of the proceeding is made.

(b) The ALJ has the authority to—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this part;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact; and

(13) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone.

(c) The ALJ does not have the authority to—

(1) Find invalid or refuse to follow Federal statutes or regulations or secretarial delegations of authority;

(2) Enter an order in the nature of a directed verdict;

(3) Compel settlement negotiations;

(4) Enjoin any act of the Secretary;

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion,

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case where the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act, or

(7) Review the exercise of discretion by the OIG to impose a CMP, assessment or exclusion under part 1003 of this chapter.

[57 FR 3350, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993]

§ 1005.5 Ex parte contacts.

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking

routine questions concerning administrative functions or procedures.

§ 1005.6 Prehearing conferences.

(a) The ALJ will schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this part;

(9) The time and place for the hearing;

(10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings; and

(11) Potential settlement of the case.

(c) The ALJ will issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 1005.7 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term documents includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system will be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section will not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) After a party has been served with a request for production of documents, that party may file a motion for a protective order.

(2) The ALJ may grant a motion for a protective order if he or she finds that the discovery sought—

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that discovery should be allowed is on the party seeking discovery.

[57 FR 3350, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993]

§ 1005.8 Exchange of witness lists, witness statements and exhibits.

(a) At least 15 days before the hearing, the ALJ will order the parties to exchange witness lists, copies of prior written statements of proposed witnesses and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 1005.16.

(b) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ will determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of such evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure to timely exchange the information

listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief:

(i) The testimony of any witness whose name does not appear on the witness list, and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of such evidence would cause substantial prejudice to the objecting party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless another party objects within a reasonable period of time prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 1005.9 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of an individual may also require the individual to produce evidence at the hearing in accordance with § 1005.7.

(c) When a subpoena is served by a respondent or petitioner on a particular individual or particular office of the OIG, the OIG may comply by designating any of its representatives to appear and testify.

(d) A party seeking a subpoena will file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. Such request will:

(1) Specify any evidence to be produced,

(2) Designate the witnesses, and

(3) Describe the address and location with sufficient particularity to permit such witnesses to be found.

(e) The subpoena will specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena will serve it by delivery to the individual named, or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(h) The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in section 205(e) of the Social Security Act (42 U.S.C. 405(e)).

§ 1005.10 Fees.

The party requesting a subpoena will pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage will accompany the subpoena when served, except that when a subpoena is issued on behalf of the IG, a check for witness fees and mileage need not accompany the subpoena.

§ 1005.11 Form, filing and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ will include an original and two copies.

(2) Every pleading and paper filed in the proceeding will contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper will be signed by, and will contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Secretary will, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document will be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service will be made upon such attorney in lieu of the party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, will be proof of service.

§ 1005.12 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government will be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 1005.2.

§ 1005.13 Motions.

(a) An application to the ALJ for an order or ruling will be by motion. Motions will state the relief sought, the authority relied upon and the facts alleged, and will be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions will be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ will make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 1005.14 Sanctions.

(a) The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. Such sanctions will reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(1) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(2) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(3) Striking pleadings, in whole or in part;

(4) Staying the proceedings;

(5) Dismissal of the action;

(6) Entering a decision by default; and

(7) Refusing to consider any motion or other action that is not filed in a timely manner.

(b) In civil money penalty cases commenced under section 1128A of the Act or under any provision which incorporates section 1128A(c)(4) of the Act, the ALJ may also order the party or attorney who has engaged in any of the acts described in paragraph (a) of this section to pay attorney's fees and other costs caused by the failure or misconduct.

§ 1005.15 The hearing and burden of proof.

(a) The ALJ will conduct a hearing on the record in order to determine whether the petitioner or respondent should be found liable under this part.

(b) Burden of proof in civil money penalty cases under part 1003, in Peer Review Organization exclusion cases under part 1004, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951. In civil money penalty cases under part 1003, in Peer Review Organization exclusion cases under part 1004, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951 of this chapter—

(1) The respondent bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and

(2) The IG bears the burden of going forward and the burden of persuasion with respect to all other issues.

(c) Burden of proof in all other exclusion cases. In all exclusion cases except those governed by paragraph (b) of this section, the ALJ will allocate the burden of proof as the ALJ deems appropriate.

(d) The burden of persuasion will be judged by a preponderance of the evidence.

(e) The hearing will be open to the public unless otherwise ordered by the ALJ for good cause shown.

(f) (1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under § 1005.8, additional items or information may be introduced by either party during its case-in-chief unless such information or items are—

(i) Privileged;

(ii) Disqualified from consideration due to untimeliness in accordance with § 1004.130(a)(2)(ii); or

(iii) Deemed otherwise inadmissible under § 1005.17.

(2) After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged in accordance with § 1005.8.

§ 1005.16 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing will be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing will be exchanged as provided in § 1005.8.

(c) The ALJ will exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid repetition or needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ will permit the parties to conduct such cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual engaged in assisting the attorney for the IG.

§ 1005.17 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. Such evidence is admissible regardless of whether the crimes, wrongs or acts occurred during the statute of limitations period applicable to the acts which constitute the basis for liability in the case, and regardless of whether they were referenced in the IG's notice sent in accordance with §§ 1001.2002, 1001.2003 or 1003.109.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

(j) The ALJ may not consider evidence regarding the issue of willingness and ability to enter into and successfully complete a corrective action plan when such evidence pertains to matters occurring after the submittal of the case to the Secretary. The determination regarding the appropriateness of any corrective action plan is not reviewable.

§ 1005.18 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 1005.19 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ will fix the time for filing such briefs which are not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 1005.20 Initial decision.

(a) The ALJ will issue an initial decision, based only on the record, which will contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion. In exclusion cases where the period of exclusion commenced prior to the hearing, any period of exclusion imposed by the ALJ will be deemed to commence on the date such exclusion originally went into effect.

(c) The ALJ will issue the initial decision to all parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. The decision will be accompanied by a statement describing the right of any party to file a notice of appeal with the DAB and instructions for how to file such appeal. If the ALJ fails to meet the deadline contained in this paragraph, he or she will notify the parties of the reason for the delay and will set a new deadline.

(d) Except as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(e) If an extension of time within which to appeal the initial decision is granted under § 1005.21(a), except as provided in § 1005.22(a), the initial decision will become final and binding on

the day following the end of the extension period.

§ 1005.21 Appeal to DAB.

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the DAB, the ALJ will forward the record of the proceeding to the DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

(d) There is no right to appear personally before the DAB, or to appeal to the DAB any interlocutory ruling by the ALJ.

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty, assessment or exclusion determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB's decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty, assessment or exclusion remanded by the ALJ, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k) (1) Any petition for judicial review must be filed within 60 days after the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of the DAB will be sent by certified mail, return receipt requested, to the Associate General Counsel, Inspector General Division, HHS. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Associate General Counsel receives two or more petitions within 10 days after the DAB issues its decision, the Associate General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

§ 1005.22 Stay of initial decision.

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b) (1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay

the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

§ 1005.23 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives such as Medicare carriers and intermediaries and Peer Review Organizations, is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the DAB inconsistent with substantial justice. The ALJ and the DAB at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 1006—INVESTIGATIONAL INQUIRIES

Sec.
1006.1 Scope.
1006.2 Contents of subpoena.
1006.3 Service and fees.
1006.4 Procedures for investigational inquiries.
1006.5 Enforcement of a subpoena.

AUTHORITY: 42 U.S.C. 405(d), 405(e), 1302 and 1320a–7a.

SOURCE: 57 FR 3354, Jan. 29, 1992, unless otherwise noted.

§ 1006.1 Scope.

(a) The provisions in this part govern subpoenas issued by the Inspector General, or his or her delegates, in accordance with sections 205(d) and 1128A(j) of the Act, and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128A of the Act or under any other section of the Act that incorporates the provisions of section 1128A(j).

(c) Nothing in this part is intended to apply to or limit the authority of the Inspector General, or his or her delegates, to issue subpoenas for the production of documents in accordance with 5 U.S.C. 6(a)(4), App. 3.

§ 1006.2 Contents of subpoena.

A subpoena issued under this part will—

(a) State the name of the individual or entity to whom the subpoena is addressed;

(b) State the statutory authority for the subpoena;

(c) Indicate the date, time and place that the investigational inquiry at which the witness is to testify will take place;

(d) Include a reasonably specific description of any documents or items required to be produced; and

(e) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In such event, the named entity will designate one or more individuals who will testify on its behalf, and will state as to each individual so designated that individual's name and address and the matters on which he or she will testify. The individual so designated will testify as to matters known or reasonably available to the entity.

§ 1006.3 Service and fees.

(a) A subpoena under this part will be served by—

(1) Delivering a copy to the individual named in the subpoena;

(2) Delivering a copy to the entity named in the subpoena at its last principal place of business; or

(3) Registered or certified mail addressed to such individual or entity at its last known dwelling place or principal place of business.

(b) A verified return by the individual serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, will be proof of service.

(c) Witnesses will be entitled to the same fees and mileage as witnesses in the district courts of the United States

(28 U.S.C. 1821 and 1825). Such fees need not be paid at the time the subpoena is served.

§ 1006.4 Procedures for investigational inquiries.

(a) Testimony at investigational inquiries will be taken under oath or affirmation.

(b) Investigational inquiries are nonpublic investigatory proceedings. Attendance of non-witnesses is within the discretion of the OIG, except that—

(1) A witness is entitled to be accompanied, represented and advised by an attorney; and

(2) Representatives of the OIG and the Office of the General Counsel are entitled to attend and ask questions.

(c) A witness will have an opportunity to clarify his or her answers on the record following the questions by the OIG.

(d) Any claim of privilege must be asserted by the witness on the record.

(e) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to the objection.

(f) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the OIG may seek enforcement of the subpoena under § 1006.5.

(g)(1) The proceedings will be recorded and transcribed.

(2) The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(3)(i) The transcript will be submitted to the witness for signature.

(ii) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the OIG written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(iii) Where, as provided in paragraph (g)(2) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(iv) The OIG's proposed corrections the record of transcript will be attached to the transcript.

(h) Testimony and other evidence obtained in an investigational inquiry may be used by the OIG or DHHS in any of its activities, and may be used or offered into evidence in any administrative or judicial proceeding.

§ 1006.5 Enforcement of a subpoena.

A subpoena to appear at an investigational inquiry is enforceable through the District Court of the United States and the district where the subpoenaed person is found, resides or transacts business.

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Sec.

AUTHORITY: 42 U.S.C. 1396b(a)(6), 1396b(b)(3) and 1396b(q).

SOURCE: 57 FR 3355, Jan. 29, 1992, unless otherwise noted.

§ 1007.1 Definitions.

As used in this part, unless otherwise indicated by the context:

Employ or *employee,* as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity that furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

§ 1007.3 Scope and purpose.

This part implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142). The statute authorizes the Secretary to pay a State 90 percent of the costs of establishing and operating a State Medicaid fraud control unit, as defined by the statute, for the purpose of eliminating fraud in the State Medicaid program.

§ 1007.5 Basic requirement.

A State Medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of §§ 1007.7 through 1007.13 of this part.

§ 1007.7 Organization and location requirements.

Any of the following three alternatives is acceptable:

(a) The unit is located in the office of the State Attorney General or another department of State government which has Statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing title XIX of the Act;

(b) If there is no State agency with Statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures that assure that the unit refers suspected cases of criminal fraud in the State Medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(c) The unit has a formal working relationship with the office of the State Attorney General and has formal procedures for referring to the Attorney General suspected criminal violations occurring in the State Medicaid program and for effective coordination of the activities of both entities relating to the detection, investigation and prosecution of those violations. Under this requirement, the office of the State Attorney General must agree to assume responsibility for prosecuting alleged criminal violations referred to it by the unit. However, if the Attorney General finds that another prosecuting authority has the demonstrated capacity, experience and willingness to prosecute an alleged violation, he or she may refer a case to that prosecuting authority, as long as the Attorney General's Office maintains oversight responsibility for the prosecution and for coordination between the unit and the prosecuting authority.

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.

(a) The unit must be separate and distinct from the Medicaid agency.

(b) No official of the Medicaid agency will have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(c) The unit will not receive funds paid under this part either from or through the Medicaid agency.

(d) The unit will enter into an agreement with the Medicaid agency under which the Medicaid agency will agree to comply with all requirements of § 455.21(a)(2) of this title.

§ 1007.11 Duties and responsibilities of the unit.

(a) The unit will conduct a Statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan.

(b) (1) The unit will also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities.

(2) If the initial review indicates substantial potential for criminal prosecution, the unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(3) If the initial review does not indicate a substantial potential for criminal prosecution, the unit will refer the complaint to an appropriate State agency.

(c) If the unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit will either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.

(d) Where a prosecuting authority other than the unit is to assume responsibility for the prosecution of a case investigated by the unit, the unit will insure that those responsible for the prosecutive decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(e) The unit will make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and will cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(f) The unit will safeguard the privacy rights of all individuals and will provide safeguards to prevent the misuse of information under the unit's control.

§ 1007.13 Staffing requirements.

(a) The unit will employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner. The staff must include:

(1) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud; and

(3) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(b) The unit will employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

§ 1007.15 Applications, certification and recertification.

(a) *Initial application.* In order to receive FFP under this part, the unit must submit to the Secretary, an application approved by the Governor, containing the following information and documentation—

(1) A description of the applicant's organization, structure, and location within State government, and an indication of whether it seeks certification under § 1007.7 (a), (b), or (c);

(2) A statement from the State Attorney General that the applicant has authority to carry out the functions and responsibilities set forth in this part. If the applicant seeks certification under § 1007.7(b), the statement must also specify either that—

(i) There is no State agency with the authority to exercise Statewide prosecuting authority for the violations with which the unit is concerned, or

(ii) Although the State Attorney General may have common law authority for Statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under § 1007.7(b), or the formal working relationship and procedures required under § 1007.7(c);

(4) A copy of the agreement with the Medicaid agency required under § 1007.9;

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this part;

(6) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) *Conditions for, and notification of certification.* (1) The Secretary will approve an application only if he or she has specifically approved the applicant's formal procedures under § 1007.7 (b) or (c), if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of § 1007.7;

(2) The Secretary will promptly notify the applicant whether the application meets the requirements of this part and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(c) *Conditions for recertification.* In order to continue receiving payments under this part, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must—

(1) Advise the Secretary of any changes in the information or documentation required under paragraphs (a) (1) through (5) of this section;

(2) Provide projected caseload and proposed budget for the recertification period; and

(3) Include or reference the annual report required under § 1007.17.

(d) *Basis for recertification.* (1) The Secretary will consider the unit's reapplication, the reports required under § 1007.17, and any other reviews or information he or she deems necessary or warranted, and will promptly notify the unit whether he or she has approved the reapplication and recertified the unit.

(2) In reviewing the reapplication, the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.17 Annual report.

At least 60 days prior to the expiration of the certification period, the unit will submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information—

(a) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(b) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(c) The number of complaints received regarding abuse and neglect of patients in health care facilities; the number of such complaints investigated by the unit; and the number referred to other identified State agencies;

(d) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(e) The number of recovery actions initiated by the Medicaid agency under its agreement with the unit, and the total amount of overpayments actually collected by the Medicaid agency under this agreement;

(f) Projections for the succeeding 12 months for items listed in paragraphs (a) through (e) of this section;

(g) The costs incurred by the unit; and

(h) A narrative that evaluates the unit's performance; describes any specific problems it has had in connection with the procedures and agreements required under this part; and discusses any other matters that have impaired its effectiveness.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.19 Federal financial participation (FFP).

(a) *Rate of FFP.* Subject to the limitation of this section, the Secretary will reimburse each State by an amount equal to 90 percent of the costs incurred by a certified unit which are attributable to carrying out its functions and responsibilities under this part.

(b) *Retroactive certification.* The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this part. For any quarter with respect to which the unit is certified, the Secretary will provide reimbursement for the entire quarter.

(c) *Amount of FFP.* FFP for any quarter will not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) *Costs subject to FFP.* (1) FFP is available under this part for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement will be limited to costs attributable to the specific responsibilities and functions set forth in this part in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities.

(2) (i) Establishment costs are limited to clearly identifiable costs of personnel that—

(A) Devote full time to the establishment of the unit which does achieve certification; and

(B) Continue as full-time employees after the unit is certified.

(ii) All establishment costs will be deemed made in the first quarter of certification.

(e) *Costs not subject to FFP.* FFP is not available under this part for expenditures attributable to—

(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;

(2) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;

(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1007.21 Other applicable HHS regulations.

Except as otherwise provided in this part, the following regulations from 45 CFR subtitle A apply to grants under this part:

Part 16, subpart C—Department Grant Appeals Process—Special Provisions Applicable To Reconsideration of Disallowances [Note that this applies only to disallowance determinations

and not to any other determinations, e.g., over certification or recertification];

Part 74—Administration of Grants;

Part 75—Informal Grant Appeals Procedures;

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services, Effectuation of title VI of the Civil Rights Act of 1964;

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80;

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance;

Part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance.

PART 1008—ADVISORY OPINIONS BY THE OIG

Subpart A—General Provisions

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

Subpart C—Advisory Opinion Fees

Subpart D—Submission of a Formal Request for an Advisory Opinion

Subpart E—Obligations and Responsibilities of the OIG

Subpart F—Scope and Effect of OIG Advisory Opinions

AUTHORITY: 42 U.S.C. 1320a-7d(b).

SOURCE: 62 FR 7357, Feb. 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§1008.1 Basis and purpose.

(a) This part contains the specific procedures for the submission of requests by an individual or entity for advisory opinions to, and the issuance of advisory opinions by, the OIG, in consultation with the Department of Justice (DoJ), in accordance with section 1128D(b) of the Social Security Act (Act), 42 U.S.C. 1320a-7d(b). The OIG will issue such advisory opinions based on actual or proposed factual circumstances submitted by the requesting individual or entity.

(b) An individual or entity may request an advisory opinion from the OIG regarding on any of 5 specific subject matters described in §1008.5 of this part.

(c) The requesting party must provide a complete description of the facts as set forth in subpart B of this part, and pay the costs to the OIG of processing the request for an advisory opinion as set forth in subpart C of this part.

(d) Nothing in this part limits the investigatory or prosecutorial authority of the OIG, DoJ or any other agency of the Government.

§1008.3 Effective period.

The provisions in this part are applicable to requests for advisory opinions submitted on or after February 21, 1997, and before August 21, 2000, and to any requests submitted during any other time period for which the OIG is required by law to issue advisory opinions.

§ 1008.5 Matters subject to advisory opinions.

(a) An individual or entity may request an advisory opinion from the OIG regarding—

(1) What constitutes prohibited remuneration within the meaning of section 1128B(b) of the Act;

(2) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in section 1128B(b)(3) of the Act for activities that do not result in prohibited remuneration;

(3) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in § 1001.952 of this chapter for activities that do not result in prohibited remuneration;

(4) What constitutes an inducement to reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries; and

(5) Whether any activity, or proposed activity, constitutes grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act.

(b) *Exceptions.* The OIG will not address through the advisory opinion process—

(1) What the fair market value will be, or what the fair market value was paid or received, for any goods, services or property; and

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

§ 1008.11 Who may submit a request.

Any individual or entity may submit a request to the OIG for an advisory opinion regarding an existing arrangement or one which the requestor in good faith specifically plans to undertake. The requestor must be a party to the arrangement, or proposed arrangement, that is the subject of the request.

§ 1008.15 Facts subject to advisory opinions.

(a) The OIG will consider requests from a requesting party for advisory opinions regarding the application of specific facts to the subject matters set forth in § 1008.5(a) of this part. The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake. The plans may be contingent upon receiving a favorable advisory opinion. The advisory opinion request should contain a complete description of the arrangement that the requestor is undertaking, or plans to undertake.

(b) Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.

(c) An advisory opinion request will not be accepted when—

(1) The request is not related to a named individual or entity;

(2) The same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing or collateral inquiry.

§ 1008.18 Preliminary questions suggested for the requesting party.

(a) The OIG may establish and maintain a set of questions corresponding to the categories of opinion subject matter as set forth in § 1008.5(a) of this part as appropriate. The questions will be designed to elicit specific information relevant to the advisory opinion being sought; however, answering the questions is voluntary.

(b) Questions the OIG suggests the requestor to address may be obtained from the OIG. Requests should be made in writing, specify the subject matter and be sent to the headquarter offices of the OIG.

(c) When submitting a request for an advisory opinion, a requestor may answer the questions corresponding to the subject matter for which the opinion is requested. The extent to which any of the questions is not fully answered may effect the content of the advisory opinion.

Subpart C—Advisory Opinion Fees

§ 1008.31 OIG fees for the cost of advisory opinions.

(a) *Responsibility for fees.* The requestor is responsible for paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion.

(b) *Initial payment.* A request for an advisory opinion must be accompanied by a check or money order payable to the Treasury of the United States for $250. This initial payment is non-refundable.

(c) *Calculation of costs.* Prior to the issuance of the advisory opinion, the OIG will calculate the costs to be incurred by the Department in responding to the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who have worked on the request in question, as well as administrative and supervisory support for such persons. The OIG has the exclusive authority to determine the cost of responding to a request for an advisory opinion and such determination is not reviewable or waivable.

(d) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(3) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, the OIG will notify the requestor.

(3) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor makes a written request for the OIG to continue processing the request. Any delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request.

(4) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the OIG attributable to processing the request for an advisory opinion up to that point.

(5) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received.

(e) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 1008.33.

(2) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

§ 1008.33 Expert opinions from outside sources.

(a) The OIG may request expert advice from qualified sources on non-legal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as peer review organizations, to obtain medical opinions on specific issues.

(b) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in § 1008.31(e), the requestor must pay the estimated cost of the expert advice.

(c) Once payment is made for the cost of the expert advice, the OIG will arrange for a prompt expert review of the issue or issues in question.

Subpart D—Submission of a Formal Request for an Advisory Opinion

§ 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarter offices of the OIG.

(b) Each request for an advisory opinion must include—

(1) The identities, including the names and addresses, of the requestor and of all other actual and potential parties, to the extent known to the requestor to the arrangement that is the subject of the request for an advisory opinion;

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in § 1008.5 of this part for which the advisory opinion is requested;

(4) A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,[1] including—

(i) Background information,

(ii) Complete copies of all operative documents, and

(iii) Detailed statements of all collateral or oral understandings, if any;

(5) All Medicare and Medicaid provider numbers used by all parties to the arrangement;

(6) Signed certifications by the requestor, as described in § 1008.37 of this part; and

(7) A check or money order payable to the Treasury of the United States in the amount of $250, as discussed in § 1008.31(b) of this part.

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion will supply full and complete information as to the identity of each entity owned or controlled by the indivudual, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social Security Act (42 U.S.C. 1320a–3(a)(1)) and part 420 of this chapter.

§ 1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.''

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification: ''The arrangement described in this request for an advisory opinion is one that [the requestor] in good faith plans to undertake.'' This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase ''if the OIG issues a favorable advisory opinion'' should be added to the certification.

(c) The certification(s) will be signed by—

(1) The requestor, if the requestor is an individual;

(2) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation; or

(3) The managing partner of the requestor, if the requestor is a partnership.

§ 1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by § 1008.36 of this part, or the OIG believes it needs more

[1] The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.

information prior to rendering an advisory opinion, the OIG may, at any time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing, signed by the same person who signed the initial request and certified by this person to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in § 1008.37 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

§ 1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§ 1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in § 1008.31(d) of this part. The OIG reserves the right to retain any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.

Subpart E—Obligations and Responsibilities of the OIG

§ 1008.41 OIG acceptance of the request.

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination of whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

(3) Decline to formally accept the request.

(c) If the requestor provides the additional information requested, or otherwise resubmits the request, the OIG will process the resubmission in accordance with paragraphs (a) and (b) of this section as if it was an initial request for an advisory opinion.

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in § 1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.

§ 1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued, once payment is received, when it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts known to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG's opinion regarding the subject matter of the request based on the facts provided and known to the OIG.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the business day next following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount until the

time when the OIG receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

(iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

(d) After the OIG has notified the requestor of the full amount owed and the OIG has received full payment of that amount, the OIG will issue the advisory opinion and promptly mail it to the requestor by regular first class U.S. mail.

§ 1008.45 Rescission.

Any advice given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind or revoke the action. Notice of such rescission or revocation will be given to the requestor so that the individual or entity may discontinue the course of action taken in accordance with the OIG advisory opinion. The OIG will not proceed against the requestor with respect to any action taken in good faith reliance upon the OIG advice under this part, where all the relevant facts were fully, completely and accurately presented to the OIG, and where such action was promptly discontinued upon notification of rescission or revocation of the OIG approval.

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarter offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared in the OIG, DoJ or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part will be exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion will be available to the public to the extent authorized by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to issue a press release or otherwise publicly disclose the identity of the requesting party or parties, and the nature of the action taken by the OIG upon the request.

Subpart F—Scope and Effect of OIG Advisory Opinions

§ 1008.51 Exclusivity of OIG advisory opinions.

The only method for obtaining a binding advisory opinion regarding any of the subject matters set forth in § 1008.5(a) is through the procedures described in this part. No binding advisory opinion, oral or written, has or may be issued by the OIG regarding the specific matters set forth in § 1008.5(a) except through written opinions issued in accordance with this part.

§ 1008.53 Affected parties.

An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.

§ 1008.55 Admissibility of evidence.

(a) The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A or 1128B of the Act.

(b) An advisory opinion not issued to a person may not be introduced into evidence to prove that person did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

§ 1008.59 Range of the advisory opinion.

(a) An advisory opinion will state only the OIG's opinion regarding the subject matter of the request. If the arrangement for which an advisory opinion is requested is subject to approval or regulation by any other agency, such advisory opinion will not be taken to indicate the OIG's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion issued under this part will not bind or obligate any agency other than the Department. It will not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.